DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K_____

Date:
To: The Record Office:
From: Division:

510(k) Holder:
Device Name:
Contact:
Phone:
Fax:
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce (device name) into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)			
Truthful and Accuracy Statement			
510(k) Summary or 510(k) Statement			
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?			
Is the device an implant (implanted longer than 30 days)?			
Does the device design use software?			
Is the device sterile?			
Is the device reusable (not reprocessed single use)? Are “cleaning” instructions included for the end user?			

IV. Indications for Use

V. Predicate Device Comparison

VI. Labeling

VII. Sterilization/Shelf Life/Reuse

VIII. Biocompatibility

IX. Software

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

XI. Performance Testing – Bench

XII. Performance Testing – Animal

XIII. Performance Testing – Clinical

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See the Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" and "A Suggested Approach to Resolving Least Burdensome Issues"

XVI. Contact History

XVII. Recommendation

Regulation Number: 21 CFR XXX.XXXX **[Only one regulation can be used.]**
Regulation Name:

Regulatory Class: Class I, II, III, or Unclassified **[Should correspond to regulation.]**
Product Code: XYZ **[Note: The first code should correspond with the regulation and class thereafter, multiple product codes can be used even if they fall under a different regulation and class.]**

Reviewer	Date
Branch Chief	Date